

AMENDMENTS TO THE DRAWINGS

The attached sheet of drawings includes changes to Figures 1 and 2. This sheet, which includes Figures 1 and 2, replaces the original sheet including Figures 1 and 2.

Attachment: Replacement Sheet

REMARKS

Favorable reconsideration of this application, in light of the preceding amendments and following remarks, is respectfully requested.

Claims 1-22 are pending in this application. By this Amendment, claim 1 is amended. Claims 1, 7 and 17 are the independent claims. Claims 21-23 are newly added. Example support for the amendments herein may be found at Para. [1-8] and Figs. 1-2 of Applicants' application.

Information Disclosure Statement

Applicants note with appreciation the Examiner's indication that the references cited in the Information Disclosure Statement filed on August 26, 2006 have been considered.

Drawings

The drawings are objected to under 37 C.F.R. 1.121(d) because the drawings contained words which were not in English.

Applicants have amended the drawings to replace the non-English terms. Withdrawal of the objection is respectfully requested.

Rejections under 35 U.S.C. § 112

Claims 17-20 are rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention.

Specifically, the Examiner asserts that claims 17-20 does not include the phrase “means for” or “step for” to properly invoke 35 U.S.C. §112. Applicants disagree.

Claim 17 recites, *inter alia*, “*memory means, assigned to the patient, for at least one of study-related and patient-related data; input means for storing data in the memory means; and reading means, accessible by a non-study doctor assigned to the patient, for reading the data out from the memory means*”. Accordingly, each claim element of claim 17 includes the proper “means for” terminology. Claims 18-20 are patentable by virtue of their dependency on claim 17.

Therefore, Applicants respectfully request the rejection to claims 17-20 under 35 U.S.C. §112 be withdrawn

Rejections under 35 U.S.C. § 101 and Summary of Brief Teleconference

Claims 1-6 and 11-14 are rejected under 35 U.S.C. 101, because the claimed invention is directed to non-statutory subject matter.

Applicants thank the Examiner for the brief teleconference of October 6, 2009, discussing the rejection and indicating that the Applicants’ proposed claim amendments, the content of which is reflected in the amendments to claim 1, appear to overcome the current rejection under 35 U.S.C. § 101. This summarizes the substance of the teleconference.

Accordingly, Applicants respectfully request the rejection to claims 1-6 and 11-14 under 35 U.S.C. §101 be withdrawn

Rejections under 35 U.S.C. § 102

Claims 1-20 are rejected under 35 U.S.C. § 102(b) as being anticipated by Brimm et al. (U.S. Patent No. 5,072,383). Applicants respectfully traverse this rejection for the reasons detailed below.

The Examiner relies on the hospital information system of Brimm to disclose the method of claim 1. Applicants disagree in that Brim does not disclose “[a] method for carrying out a clinical study involving a patient, comprising: storing at least one of study-related and patient-related data, to be read out from a computer by a non-study doctor assigned to the patient, in a memory during the clinical study, wherein the memory is a computer readable storage medium” as recited by amended claim 1. In fact, Brimm is completely silent with respect to clinical studies in general.

In contrast, Brimm is directed to a hospital information system having data processing system including terminals for display and data entry. (See Abstract). In the system: patient data is entered via the terminals, organized hierarchically, and displayed to individuals with proper access. (See *Id.*). Further, the hospital information system of Brimm also provides for a time-oriented task list generated from data which had been entered from physicians and nursing orders. (See *Id.*).

However, Brimm is silent with regard to, and therefore does not even include, clinical studies. Further, Brimm is also does not include interfacing with physicians that have no connection to a particular clinical study or a non-study doctor.

Moreover, the hospital information system of Brimm relates to the hospital's internal processes. (See Abstract and column 3: lines 58-68 and column 4: lines 1-49) For instance, all the data associated with one patient is available within the hospital information system. Accordingly, any person within the hospital may gain access to the patient's data stored in the hospital information system. Nevertheless, Brimm is

does not contemplate, and therefore does not include, a physician who is external to the hospital information system, hence a non-study doctor.

Accordingly, Brimm does not include or even fairly suggests “[a] method for carrying out a clinical study involving a patient, comprising: storing at least one of study-related and patient-related data, to be read out from a computer by a non-study doctor assigned to the patient, in a memory during the clinical study, wherein the memory is a computer readable storage medium” as recited by amended claim 1.

Therefore, Brimm fails to teach each and every element of independent claim 1, and therefore, Brimm does not anticipate claim 1.

Claims 7 and 17 contain features somewhat similar to those discussed above in regard to claim 1, and therefore, claims 7 and 17 are patentable over Brimm for at least somewhat similar reasons as claim 1. Claims 2-6, 8-16, and 18-20 are patentable at least by virtue of their dependency from claims 1, 7, and 17.

For at least the foregoing reasons, Applicants respectfully request that the Examiner withdraw the rejection of claims 1-20 under 35 U.S.C. §102(b).

New Claims

Claims 21-23 are newly added and believed to distinguish over the cited art.

CONCLUSION

In view of the above remarks and amendments, the Applicants respectfully submit that each of the pending objections and rejections has been addressed and overcome, placing the present application in condition for allowance. A notice to that effect is respectfully requested. If the Examiner believes that personal communication will expedite prosecution of this application, the Examiner is invited to contact the undersigned.

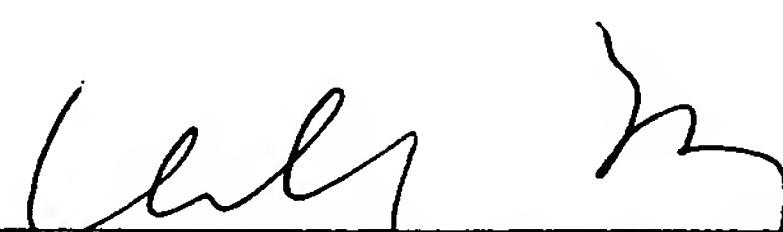
Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact Donald J. Daley, at the telephone number of the undersigned below.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 08-0750 for any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17; particularly, extension of time fees.

Respectfully submitted,

HARNESS, DICKEY, & PIERCE, P.L.C.

By


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